

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-8, 22 and 23 are pending in the application, with claim 1 being the sole independent claim. Claim 22 has been amended. Support for the amendment to claim 22 may be found, *inter alia*, at page 11, lines 28-30 of the specification. The specification has been amended to correct a minor spelling error. Support for this amendment can be found throughout the specification, for example, in claim 2 as originally presented. No new matter is added by way of this amendment. It is respectfully requested that the amendment be entered and considered.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Objection to the Abstract***

The Examiner has objected to the Abstract because allegedly it does not specifically reflect the presently claimed invention. *See* Office Action, page 2.

According to 37 C.F.R. § 1.72(b), "[t]he purpose of the abstract is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure." The Examiner has not specifically explained why the Abstract is considered not to accurately reflect the "nature and gist of the technical disclosure."

The present Abstract recites:

Methods and compositions for the treatment of microbial infection, and in particular meningococcal disease, comprise a commensal *Neisseria* or an extract of a commensal *Neisseria*. *Further methods and compositions comprise commensal Neisseria which express genes from virulent strains of Neisseria and/or heterologous gene products from non-neisserial sources.* Such compositions are used in vaccine preparations for the treatment of microbial infection.

See specification, page 47, emphasis added.

The present claims are directed to methods of preparing a composition comprising an isolated heterologous gene product and a pharmaceutically acceptable carrier. The heterologous gene product is specified as being selected from (1) a product of a gene of a non-*Neisserial* organism and (2) a product of a gene of a pathogenic *Neisseria*. The compositions made by the claimed methods are useful as vaccine preparations for the treatment of microbial infection. *See, e.g., specification, page 4, lines 27-34.* Thus, Applicants believe that the present abstract accurately conveys "the nature and gist of the technical disclosure," as required by 37 C.F.R. § 1.72(b).

Applicants therefore respectfully request that the Examiner withdraw the objection to the Abstract or at least explain why the Abstract is considered not to accurately reflect the "nature and gist of the technical disclosure" so that specific corrections, if necessary, can be made.

***Objection to the Title***

The Examiner objected to the Title as not descriptive and required a new Title that is clearly indicative of the invention to which the claims are directed. *See* Office Action, page 2.

According to 37 C.F.R. § 1.72(a), "[t]he title of the invention may not exceed 500 words and must be as short and specific as possible." The M.P.E.P. instructs that "[w]here the title is not descriptive of the invention claimed, the examiner should require the substitution of a new title that is clearly indicative of the invention to which the claims are directed." *See* M.P.E.P. § 606.01. The Examiner has not indicated how or why the present Title is deemed not descriptive of the invention claimed.

The present Title of the invention is "Neisserial Vaccine Compositions and Methods." As noted above, the present claims are directed to methods of preparing compositions that can be used as vaccines. Thus, Applicants believe that the present Title is sufficiently descriptive of the invention claimed. Applicants therefore respectfully request that the objection to the Title be withdrawn, or that the Examiner at least explain why it is believed that the present title is deemed not descriptive of the invention claimed and/or suggest a new Title. *See* M.P.E.P. § 606.01.

***Objection to the Specification***

The Examiner objected to the disclosure because "perflava" is spelled incorrectly at page 3, line 27 of the specification. *See* Office Action, page 2. Applicants have corrected the spelling error and therefore request withdrawal of this objection.

***Claim Rejections Under 35 U.S.C. § 112, First Paragraph***

The Examiner rejected claim 4 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. *See* Office Action, pages 3-4. Specifically, the Examiner alleged that the specification only supports a fragment of transferrin binding protein, and that there is no support for fragments of Cu,Zn-SOD, NspA, porin, or an outer membrane protein. *See* Office Action at page 3. Applicants respectfully traverse this rejection.

Applicants respectfully assert that the application disclosure is not limited to fragments of transferrin binding protein as the Examiner alleged. Claim 4, as originally filed, literally supports fragments of gene products (a)-(e) recited in present claim 4. Originally filed claim 4 recites:

[t]he method of claim 3, wherein the commensal *Neisseria* expresses a gene which encodes a protein from *N. meningitidis* selected from the group consisting of transferrin binding protein; a Cu,Zn-SOD; an NspA; a porin; an outer membrane protein *and fragments thereof*.

*See* specification at page 44, emphasis added. It is clear from this original claim language that the "fragments thereof" refer to *all* of the members of the recited group, *i.e.*, fragments of transferrin binding protein, fragments of Cu,Zn-SOD, fragments of NspA, fragments of a porin, and fragments of an outer membrane protein.

Moreover, other parts of the specification clearly and unambiguously indicate that the "fragments thereof" language of original claim 4 applies to all heterologous gene

products, including those recited in parts (a)-(e) of present claim 4. For example, the specification describes the heterologous gene products as follows:

[h]eterologous gene products of the invention typically include peptides, proteins and antisense sequences that are coded for by a gene sequence that is not native to the commensal *Neisseria*. Typical heterologous gene products of the invention include, for example, bacterial proteins, viral proteins or surface peptides, antigens and antibodies and *fragments thereof*. The heterologous gene product of the invention may also be any antigen found in a pathogenic organism.

*See* specification at page 10, lines 27-33, emphasis added. Further, the specification lists transferrin binding protein, Cu,Zn-SOD, Neisserial surface protein A, porin, and outer membrane proteins as exemplary heterologous proteins. *See* specification at page 8, lines 9-11. As such, it cannot be disputed that the specification conveys with reasonable clarity that the inventors, at the time the application was filed, were in possession of the method of claim 4, wherein the heterologous gene product is a fragment of any one of (a)-(e) recited in present claim 4.

Based on the forgoing, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 4 under 35 U.S.C. § 112, first paragraph.

***Claim Rejection Under 35 U.S.C. § 112, Second Paragraph***

The Examiner rejected claims 22 and 23 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in the recitation of "isolating an outer membrane vesicle." *See* Office Action, page 3. The Examiner alleged that it is unclear how these outer membrane vesicles are made and if the outer membrane vesicles are part of the

*Neisseria* of step (c). The Examiner further inquired as to how the gene product gets into the outer membrane vesicle. Applicants respectfully traverse this rejection.

Regarding how the outer membrane vesicles are made, Applicants respectfully assert that one of ordinary skill in the art would clearly understand the meaning of the expression "isolating an outer membrane vesicle" as well as the various methods encompassed by this expression. For instance, Applicants note that suitable methods for isolating outer membrane vesicles are described in Example 2 (which relates to the well known lithium acetate method of preparing outer membrane vesicles). Other methods are also well known in the art. *See, e.g.*, specification at page 38, lines 10-13.

Regarding the Examiner's concern as to whether the outer membrane vesicles are part of the *Neisseria* of step (c), Applicants note that claim 22 has been amended to explicitly specify that the outer membrane vesicles are isolated from the *Neisseria* of step (c) of claim 1.

Finally, with regard to the Examiner's concern as to how the heterologous gene product gets into the outer membrane vesicle, Applicants submit that a person of ordinary skill in the art would readily comprehend this aspect of claim 22. Nonetheless, to expedite allowance of this application, Applicants have amended claim 22 to recite that the heterologous gene product comprises an outer membrane protein or is directed to the outer membrane of said *Neisseria* by a signal sequence. Signal sequences are well known in the art, and are discussed on page 11, lines 28-33 of the specification. Applicants assert that, in view of the current claim language, a person of ordinary skill would clearly appreciate that the heterologous gene product is directed to the outer membrane by virtue of comprising an outer membrane protein or by a signal sequence.

Based on the forgoing, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 22 and 23 under 35 U.S.C. § 112, second paragraph.

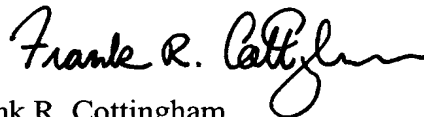
### ***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned directly at the telephone number below.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

Date: FEB. 28, 2006

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600